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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/557,196	04/12/2006	**Palaniswamy Sunder Raj**	687-140	5509

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EXAMINER	
BAEK, BONG-SOOK	
ART UNIT	**PAPER NUMBER**
4161	
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04/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/557,196	RAJ ET AL.	
	Examiner	Art Unit	
	BONG-SOOK BAEK	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-59* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Status of the Claims

Claims 1-59 are currently pending and are the subject of restriction and/or election requirement. Claims 60-71 have been canceled.

Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-8, 14-27, 30-33, and 42-58, drawn to a composition of triprolindine in combination with at least one further active pharmaceutical agent.

Group II, claims 1-13, 17-29, and 34-58, drawn to a method of using the composition for the diagnosis, prophylaxis and/or the treatment of neuropathy and related disorders.

Group III, claims 1-8, 17-27, and 42-59, drawn to a method of making the composition.

It is noted claims 1-8, 17-27, and 42-58 are use claims, which are non-statutory. Applicant is required to cancel or amend said claims to be either product or process claims in accordance with Group I, II, or III.

The Inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature in all groups is the composition of triprolindine in combination with at least one further active pharmaceutical agent. This element cannot be a special technical feature because the element is shown in the prior art. US patent 6,245,785 B1 teaches the composition recited in the instant claim 1 (column 3, lines 32-41 and example 1). In addition, US patent 6,245,785 B1 also teaches the method of making the composition recited in the instant claim 59 in Group III (claim 18). Therefore, Group I, II, and III do not share special technical feature with one another. As such, unity between the above Groups I, II, and III is broken.

Species Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

1) If applicant selects Group I, II and III, one species from different purposes of the treatment for sleep disorders and related adverse side effects set forth in claims 1-

11 and 13-17 should be selected to be fully responsive. The following is a list of different purposes:

-Enabling an individual to wake refreshed after sleeping,

-Treating or preventing of grogginess, drowsiness or lethargy on waking from sleeping,

-Prolonging and/or enhancing sleep and/or sleep quality

The species listed above do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features because they are distinct purposes which can be addressed by different methods and with different medicaments. In addition, WO 2003/032912 teaches the method of treatment associated with a number of adverse side effects after the treatment of sleep disorders (page 1, line 22-page 2, line 6).

2) If applicant selects Group I, II and III, one species from different active pharmaceutical agents set forth in claims 18-20, and 26 should be selected to be fully responsive. The following is a list of different active pharmaceutical agents:

-An active agent used in the treatment of pain relief, migraines, allergies, colds, flu, coughs or anxiety; an active agent used as an anesthetic, antiviral agent, antidepressive agent, decongestant or disinfectant; or an active agent used in women's health (claim18)

-Ibuprofen, Fluribiprofen, Ketoprofen, Aspirin, Paracetamol, Aceclofenac, Codeine, Naproxen, Indomethacin, Diclofenac, Cox II, Meloxicam, Nitric oxide, Caffeine, Acrivastine, Cetirizine, Loratadine, Fexofenadine, Terfenadine, Beclomethasone, Hydrocortisone, Triptan, Almotriptan, Rizatriptan, Naratriptan, Sumatriptan, Zolmatriptan, Domperidone, Acetylcysteine, Menthol, Ambroxol, Carbocisteine, Dextromethorphan, Guaiphenesin, Ipecacuanha, Phenylpropanolamine, Liquorice, Marshmallow, Squill,

Honey, Glycerine, Aniseed, Benzocaine, Lidocaine, Amantadine, Aciclovir, Famciclovir, Ganciclovir, Rimantadine, Penciclovir, Tribavirin, Valaciclovir, Neuraminidase inhibitors, Zanamir, Oseltamir, Benzalkonium chloride, Cetylpyridinium chloride, Dichlorobenzyl alcohol, Amylmetacresol, Dequalinium chloride, Hexylresorcinol, Eucalyptus oil, Thymol, Calamine, Propranalol, Chamomile, Hops, Passion flower, Valarian, Melatonin, Eucalyptus, Phenylepherine, Pseudoephedrine, Cranberry and Bisphosphonates (claim 19)

-Ibuprofen, Fluribiprofen, Cox II such as meloxicam, triptans, Domperidone Ambroxol, Dextromethorphan, Guaiphenesin, Lidocaine, Amiantadine, Hexylresorcinol, dcba, amc, Propranalol, pseudoephedrine and Bisphosphonates (claim 20).

- antacids, analgesics, anti-inflammatories, antibiotics, laxatives, anorexics, antiasthmatics, antidiuretics, antiflatulents, antimigraine agents, antispasmodics, additional sedatives, antihyperactives, tranquilizers, antihistamines, decongestants, betablockers, antidepressives, hormones and combinations thereof (claim 26).

The species listed above do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features because they are distinct compounds which have various different pharmacological or physiological properties. In addition, WO 2003/032912 teaches the species recited in claim 18-20 (p9, line 1-p14, line 15).

3) If applicant selects Group I, II, and III, one species from different administration routes and formulations set forth in claims 37-40, and 43-46 should be selected to be fully responsive. The following is a list of different administration routes and formulations:

-Administration routes: orally, nasally, optically, rectally, pulmonarily, transdermally or sub-lingually (claims 37, 39, 43, and 45)

-Formulations: tablet, capsule, drink, lozenge, drops, emulsion, dry powder, suspension, pastille, patch, suppository, syrup, consumable film such as a buccal wafer, sub-lingual spray or nasal spray (claims 38, 40, 44, and 46)

The species listed above do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features because they are distinct administration routes and formulations which have different pharmacodynamic or pharmaceutical characteristics. In addition, WO 2003/032912 teaches the species recited in claims 37-40 and 43-46 (p15, lines 10-33).

4) If applicant selects Group I, II, or III, one specific species from additional compounds or carriers set forth in claims 47-55 should be selected to be fully responsive. The following is a list of different additional compounds:

-Diluents: saccharide, lactose

-Disintegrants: croscarmellose sodium

-Lubricants: magnesium stearate

-Coating agent: methylated cellulose derivatives

The species listed above do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features because they are distinct compounds which have different pharmaceutical or chemical properties and are used for different pharmaceutical

purposes. In addition, US 6,245,785 B teaches the species recited in claims 47-55 (column 3, lines 26-31).

The following claims are generic: claims 1, 14, 21-25, 27, 30-34, 42, 56-58 for Group I, claims 1, 12, 21-25, 27-29, 41-42, and 56-58 for Group II and claims 1, 21-25, 42, 56-58, and 59 for Group III.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does

not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.Any inquiry

concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached on 8:00-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bong-Sook Baek
Examiner, Art Unit 4161

Bbs

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4161